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Clarence A Green
Perman & Green LLP
425 Post Road
Fairfield, CT 06430

EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/09/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/492,214

Applicant(s)

STEMMLER ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 1/04/02 in Paper No. 9 are acknowledged and have been entered. Claims 24-32 have been cancelled. Claims 1-23 have been amended. Claims 33-41 have been added. Accordingly, claims 1-23 and 33-41 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-23 and 33-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claim lacks specific elements, i.e. label so as to effect measurement of a signal.

Claim 1 is vague and incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, it is unclear what structural cooperative relationship exists between the measurement signal and the analyte. For

example, is the measurement signal that is obtained from one of the phases, related to the concentration or kinetics of the analyte.

Claim 1 is ambiguous in reciting “each measurement signal being attributed to” because it is unclear what is encompassed by the term “attributed to” as recited in the claim.

Claim 2 is vague and indefinite in reciting “the method is an affinity assay” because it is unclear how the method is performed in the absence of affinity elements in claim 1 from which it depends, i.e. ligands, biotin, avidin.

Claim 4 is vague and indefinite in reciting “the method is conducted as an immuno-affinity assay” because it is unclear how the method is performed in the absence of immuno-affinity elements in claim 1 from which it depends, i.e. antibodies, antigens, ligands.

Claim 5 lacks clear antecedent support in reciting “the volume” and “the detection”. Further, the claim fails to specifically define what is encompassed by reciting “the volume in which the detection occurs” in the claim, i.e. the volume of the system, the volume of each phase, sample volume, etc. Please clarify.

Claim 6 is vague and indefinite in reciting “the method is a competitive assay” because it is unclear how the method is performed in the absence of antibodies or ligand partners in claim 1 from which it depends, i.e. antibodies, antigens.

Claim 7 is vague and indefinite in reciting “the method is a sandwich assay” because it is unclear how the method is performed in the absence of antibodies or ligand partners in claim 1 from which it depends, i.e. antibodies, antigens.

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Claim 8 lacks antecedent support in reciting "the reactant". Claim 8 is further indefinite in reciting "the reactant carries a label for generating" because it is unclear what Applicant intends to encompass in reciting "carries", i.e. "the reactant is conjugated to a label".

Claim 14 has improper antecedent basis problem in reciting "a well". Further, the term "is provided" appears to detract clarity from the claim.

Claim 15 has improper antecedent basis problem in reciting "a well".

Claim 16 has improper antecedent basis problem in reciting "a well".

Claim 18, line 2 has improper antecedent basis problem in reciting "a well".

Claim 18, line 3, lacks clear antecedent support in reciting, "the wall and floor".

Claim 20, as amended, has improper antecedent problem in reciting "a label".

Claim 22 is confusing because it is unclear what Applicant intends to encompass in reciting, "the stimulating light beam is conducted via the sample".

Claim 38 is ambiguous because it is unclear how the beam is differentially selected so as to excite only one of the phases in the sample.

Claim 39 has improper antecedent basis problem in reciting, "the well of a carrier".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-4, 6-14, 17-18, 20, 23, and 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hargreaves (US 6,121,055) for reason of record.

4. Claims 1, 8-13, 17-18, 20, and 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Te Koppele et al. (US 6,121,055) for reason of record.

5. Claims 1-2, 4, 6, 8-13, 17-18, 20, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Saunders et al. (US 5,674,699) for reason of record.

6. Claims 1-2, 4, 8-9, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Komives et al. (US 5,510,247) for reason of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5, 15-16, 19, 21-22, 33, and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargreaves (US 6,121,055) in view of Dixon et al. (US 5,381,224) for reason of record.

Response to Arguments

8. Applicant's arguments filed 1/4/02 have been fully considered but they are not persuasive.

A) Applicant argues that Hargreaves differs from the instant invention because detection of analyte in Hargreaves is based on the separation of the bound label from the unbound label.

In response, Hargreaves, indeed, teaches exciting fluorescent labeled complexed binding pairs from the bottom region of the primary and secondary layers and taking measurement signals therefrom using a detector; such embodiment prevents excitation of unbound or free labels in the system during detection, such as taught in the claimed invention (see column 29, lines 26-29).

B) Applicant argues that Te Koppele differs from the instant invention because detection of analyte in Te Koppele is based on the separation of the bound label from the unbound label.

In response, Te Koppele only optionally separates the liquid phase from the solid phase material. Te Koppele teaches irradiating only the solid phase to measure a fluorescent signal (see columns 3, 7, and 8). The fluorescence quenched substrate on the wells of the solid phase, i.e. microtiter plates, remain immobilized upon cleavage.

C) Applicant argues that Saunders differs from the instant invention because only one phase is present in the method during detection of the analyte.

Contrary to Applicant's argument, both phases are present in the mixture of Saunders during detection of the analyte. Specifically, Saunders discloses qualitatively or quantitatively measuring analyte in a sample comprising contacting a sample solution containing the analyte with reactants (particles and affinity reagent) to form a mixture then fractionating the mixture to form two different phases including a solid phase (particle rich fraction) and a liquid phase (particle free fraction) in fluid contact within a sample carrier in the form of a microtiter plate. Saunders teaches optically reading measurement signals from each of the phases while present in parallel within the carrier (see claim 1).

D) Applicant argues that Komives differs from the instant invention because the analytes are detected via dynamic light scattering in one phase after the separation of the different phases.

In response, Komives appears to clearly anticipate the claimed invention as described by Applicant. Alternatively, claim 1 does not appear to exclude detecting analytes by dynamic light scattering such as taught by Komives.

E) Applicant argues that Dixon relates to optical detection systems, but does not disclose a method for the qualitative and quantitative detection of analytes or the use of quenchers in fluorescence spectra.

In response, Dixon was incorporated with the teaching of Hargreaves in an obviousness rejection. Specifically, Hargreaves discloses a two-phase system wherein a first aqueous phase comprises an assay mixture containing the analyte, reactants, label, and a primary layer which extends generally transversely across within a second solid phase which comprises a well on a microtiter plate. Hargreaves teaches exciting fluorescent labeled complexed binding pairs from the bottom region of the primary and secondary layers and taking measurement signals therefrom using a detector; such embodiment prevents excitation of unbound or free labels in the system. Dixon is incorporated therewith for the teaching of a laser system capable of making signal measurements simultaneously or sequentially on the same specimen using a combination of the aforementioned contrast mechanisms. The system is used for tier fluorescence imaging and measurement, as well as for mapping of layers where luminescence or fluorescence spectrum is measured at each pixel position, as in spatially resolved and spectrally resolved measurements. It would have been obvious to one of ordinary skill in the art at the time

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of the instant invention to use the imaging and detection system taught by Dixon in the heterogeneous assay methods of Hargreaves because the detection systems taught in Hargreaves are generic with respect to the light source and detector used in exciting and measuring signals from fluorescent and laser dye labels and Dixon specifically taught application of the scanning laser beam imaging or mapping system in macroscopic biological specimens (assay mixtures) that fluoresce upon excitation by laser radiation including DNA sequencing in fluorescent gels (solid).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

9. For reason aforementioned, no claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
March 25, 2002




LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/01/02